

CERTIFICATE OF ANALYSIS

PRODUCT : DILTIAZEM HCl (MICRONISED)		COMPENDIA : Ph.Eur.-8.0
BATCH NO. : DIL/M-01015		QUANTITY : 500 Kg
MFG. DATE : JANUARY.2015		EXP. DATE : DECEMBER.2019
QC A.R. No.: FP/017/2015		
TESTS	RESULTS	SPECIFICATIONS
01. CHARACTERS		
i. Appearance	White, crystalline powder.	White or almost white, crystalline powder.
ii. Solubility	Freely soluble in water, in methanol and in methylene chloride, slightly soluble in anhydrous ethanol.	Freely soluble in water, in methanol and in methylene chloride, slightly soluble in anhydrous ethanol.
iii. Melting point	Melted at 213°C with decomposition.	Melts at about 213° C with decomposition.
02. IDENTIFICATION		
IR Absorption	Concordant with working standard	IR Absorption spectrum of the sample is concordant with that of the Diltiazem hydrochloride CRS / working standard.
CHLORIDES	Positive	It gives reaction to chlorides.
03. APPEARANCE OF SOLUTION	Clear and colourless	Clear and colourless.
04. pH	4.6	4.3 to 5.3
05. SPECIFIC OPTICAL ROTATION	+119°	+ 115° to + 120°
06. RELATED SUBSTANCES		
i. Impurity F	Not Quantified	Not more than 0.3% w/w
ii. Unspecified Impurities	Not Quantified	Not more than 0.10% w/w each
iii. Total Impurities	Not Quantified	Not more than 0.30% w/w
07. HEAVY METALS	Less than 10 ppm	Not more than 10 ppm
08. LOSS ON DRYING	0.21%	Not more than 0.50% w/w
09. SULPHATED ASH	0.03%	Not more than 0.10% w/w
10. ASSAY (By Titration)	99.98%	Not less than 98.50% w/w and Not more than 101.00% w/w
(On dried basis)		
ADDITIONAL TEST:		
PARTICLE SIZE		
100%	35 Microns	100% Less than 100 Microns
Surface Area	1.92 m ² /gm	For Information
RESIDUAL SOLVENTS (BY GC-HS)		
Toluene	182 ppm	Not more than 750 ppm
Methanol	118 ppm	Not more than 500 ppm
Isopropyl Alcohol	4 ppm	Not more than 1000 ppm
Ethyl Acetate	1 ppm	Not more than 500 ppm
Bulk Density	0.27 g/ml	For Information
Tapped Density	0.51 g/ml	For Information

REMARKS: The product conforms to **Ph.Eur.-8.0 & Customer's Specifications**

Daw
Prepared by
Executive-QC

[Signature]
Checked by
Manager-QC

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Approved by
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PIRAMAL ENTERPRISES LIMITED

Result Analysis Report

Sample Name:
DILTIAZEM HCL

Sample Source & type:
Factory = PHL

Sample bulk lot ref:
DIL/M-01015(FP-017-2015)

SOP Name:
DILTIAZEM HCL

Measured by:
MAHESH

Result Source:
Measurement

Measured:
20 January 2015 PM 04:58:28

Analysed:
20 January 2015 PM 04:58:30

Particle Name:
DILTIAZEM HCL

Particle RI:
1.500

Dispersant Name:

Accessory Name:
Scirocco 2000

Absorption:
0.001

Dispersant RI:
1.000

Analysis model:
General purpose

Size range:
0.020 to 2000.000 um

Weighted Residual:
0.901 %

Sensitivity:
Normal

Obscuration:
4.22 %

Result Emulation:
Off

Concentration:
0.0004 %Vol

Span :
2.248

Uniformity:
0.69

Result units:
Volume

Specific Surface Area:
1.92 m²/g

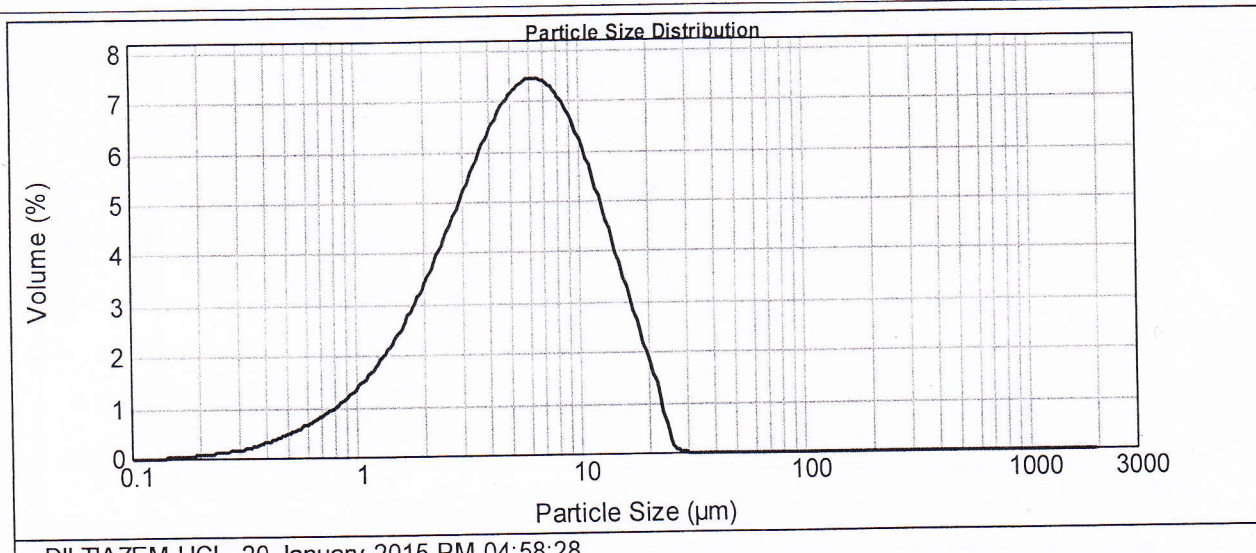
Surface Weighted Mean D[3,2]:
3.121 um

Vol. Weighted Mean D[4,3]:
6.560 um

d(0.1): 1.523 um

d(0.5): 5.328 um

d(0.9): 13.502 um



Size (µm)	Vol Under %	Size (µm)	Vol Under %	Size (µm)	Vol Under %	Size (µm)	Vol Under %	Size (µm)	Vol Under %	Size (µm)	Vol Under %
0.017	0.00	2.188	17.09	8.600	72.92	21.000	98.73	130.030	100.00	831.764	100.00
0.026	0.00	2.512	20.70	9.411	76.88	22.000	99.20	149.400	100.00	954.993	100.00
0.158	0.01	2.884	24.88	9.900	79.01	23.000	99.57	150.011	100.00	1096.478	100.00
0.275	0.23	3.311	29.64	10.000	79.43	26.303	99.97	160.000	100.00	1258.925	100.00
0.316	0.35	3.802	34.98	10.200	80.23	34.674	100.00	174.000	100.00	1445.440	100.00
0.363	0.53	4.365	40.83	10.800	82.47	39.005	100.00	181.970	100.00	1659.587	100.00
0.417	0.78	5.012	47.12	11.682	85.35	43.452	100.00	208.930	100.00	1905.461	100.00
0.479	1.12	5.754	53.70	12.475	87.57	45.012	100.00	239.883	100.00	2187.762	100.00
0.631	2.11	6.930	62.74	13.062	89.01	69.824	100.00	275.423	100.00	2511.886	100.00
0.724	2.79	7.390	65.84	13.800	90.62	85.000	100.00	316.228	100.00	2884.032	100.00
0.832	3.63	7.458	66.28	14.465	91.90	97.900	100.00	363.078	100.00	3311.311	100.00
0.955	4.65	7.578	67.04	15.000	92.82	99.850	100.00	416.869	100.00	3801.894	100.00
1.096	5.89	7.874	68.85	15.790	94.02	100.000	100.00	478.630	100.00	5011.872	100.00
1.259	7.40	8.020	69.71	16.308	94.73	119.020	100.00	549.541	100.00	6606.934	100.00
1.660	11.40	8.210	70.80	17.659	96.28	125.000	100.00	630.957	100.00	7585.776	100.00
1.905	14.01	8.500	72.38	18.010	96.62	126.251	100.00	724.436	100.00	10000.000	100.00

Analysed by:

Checked by: